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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME B.V. and ORGANON USA INC., Plaintiffs, v. MSN LABORATORIES PRIVATE LIMITED; MSN LIFE SCIENCES PRIVATE LIMITED; and MSN PHARMACEUTICALS INC., Defendants.	Civil Action No. 20-3314 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck Sharp & Dohme B.V. ("Merck B.V.") and Organon USA Inc. ("Organon") (together, "Merck"), by their attorneys, bring this complaint against Defendants MSN Laboratories Private Limited ("MSN Labs"), MSN Life Sciences Private Limited ("MSN Life"), and MSN Pharmaceuticals Inc. ("MSNPI") (together, "MSN Defendants"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United

States, 35 U.S.C. § 100, *et seq*., including 35 U.S.C. § 271(e)(2), the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that arises out of MSN Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import all strengths of a purported generic version of Bridion® (sugammadex) Injection prior to the expiration of U.S. Patent No. RE44,733 ("the '733 patent").

PARTIES

2. Plaintiff Merck Sharp & Dohme B.V. ("Merck B.V.") is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Waarderweg 39, Haarlem, Netherlands 2031 BN. Merck B.V. is an indirect, wholly owned subsidiary of Merck & Co., Inc., a New Jersey corporation, which has its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

3. Plaintiff Organon USA Inc. ("Organon") is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889. Organon is a wholly owned subsidiary of Merck & Co., Inc.

4. On information and belief, Defendant MSN Laboratories Private Limited ("MSN Labs") is a corporation organized and existing under the laws of India, with a place of business at MSN House, C-24, Sanathnagar Industrial Estate, Hyderabad, Telangana, 500018, India. On information and belief, MSN Labs is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market, through various operating affiliates and subsidiaries, including MSN Life and MSNPI.

5. On information and belief, Defendant MSN Life Sciences Private Limited ("MSN Life") is a corporation organized and existing under the laws of India, with a place of business at Sy No- 21/A & 21AA, Mambapur (Village), Gummadidala (Mandal), Sangareddy (District), Telangana, 502313, India. On information and belief, MSN Life is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market.

6. On information and belief, Defendant MSN Pharmaceuticals Inc. ("MSNPI") is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 20 Duke Road, Piscataway, New Jersey 08854. On information and belief, MSNPI is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market.

7. On information and belief, MSN Life is an affiliate of MSN Labs.

8. On information and belief, MSNPI is a wholly owned subsidiary of MSN Labs and an authorized U.S. agent for MSN Labs.

9. By a letter dated March 10, 2020 ("MSN Notice Letter"), MSN Labs notified Merck that MSN Labs had submitted to the FDA ANDA No. 214368 ("MSN's ANDA") for purported generic versions of sugammadex injection, 200 mg/2 mL and 500 mg/5 mL ("MSN ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN ANDA Products in or into the United States, including New Jersey, prior to the expiration of the '733 patent.

10. On information and belief, MSN Labs, MSN Life, and MSNPI acted in

concert to prepare and submit MSN's ANDA and the MSN Notice Letter.

11. On information and belief, MSN Labs, MSN Life and MSNPI know and intend that upon approval of MSN's ANDA, MSN Labs, MSN Life and/or MSNPI will manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the MSN ANDA Products throughout the United States, including in New Jersey. On information and belief, MSN Labs, MSN Life and MSNPI are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to the MSN ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, MSN Labs, MSN Life, and MSNPI participated, assisted, and cooperated in carrying out the acts complained of herein.

12. On information and belief, MSN Life holds Drug Master File No. 33723 for sugammadex sodium.

13. On information and belief, following any FDA approval of MSN's ANDA, MSN Labs, MSN Life and MSNPI will act in concert to manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the MSN ANDA Products throughout the United States, including New Jersey.

JURISDICTION AND VENUE

14. Merck incorporates each of the preceding paragraphs 1–13 as if fully set forth herein.

15. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271, for infringement of the asserted patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

16. MSN Labs is subject to personal jurisdiction in New Jersey because, among other things, MSN Labs itself, and through its affiliate MSN Life and/or its wholly owned

subsidiary MSNPI, purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, MSN Labs itself, and through its affiliate MSN Life and/or its wholly owned subsidiary MSNPI, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, MSN Labs is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates MSN Life and/or MSNPI, and therefore the activities of MSN Life and/or MSNPI in this jurisdiction are attributed to MSN Labs.

17. MSN Labs, in concert with MSN Life and MSNPI, has committed an act of infringement in this judicial district by filing ANDA No. 214368 with the intent to make, use, sell, offer for sale, and/or import the MSN ANDA Products in or into this judicial district, prior to the expiration of the '733 patent.

18. MSN Labs' website states that MSN Labs has a portfolio that includes "100 ANDAs" and "560 DMFs." *See* msnlabs.com, About Us, Who We Are tab, *available at* http://www.msnlabs.com/who-we-are.html (last visited March 23, 2020). MSN Labs' website states that MSN Labs "has nine API and five finished dosage facilities established across Hyderabad, USA and Myanmar" and "also ha[s] offices in New Jersey – USA." *Id.* at About Us, Who We Are tab; *id.* at Research, Leader in Drug Development tab. Further, MSN Labs' website publically touts MSN Labs' presence in the USA and New Jersey, and lists MSNPI as MSN Labs' "state-of-the-art finished dosage manufacturing facility based out of Piscataway, New Jersey." *Id.* at Global Presence, MSN USA tab. Finally, MSN Labs' website lists MSN Life as one of MSN

Labs' "API Facilities." *Id.* at Contact us tab.

19. MSN Life is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, MSN Life develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

20. This Court has personal jurisdiction over MSNPI because MSNPI is a corporation with its principal place of business in New Jersey.

21. MSNPI is also subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, MSNPI develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

22. MSNPI's website states that "MSN PI is a fully owned subsidiary of the MSN group of companies" that is "based out of Piscataway, New Jersey." *See* MSNPI.com, *available at* http://msnpi.com/ (last visited March 23, 2020). MSNPI's website also states that "MSNPI develops and manufacture [*sic*] products for MSN group as well as specialized in contract development and manufacturing of high-quality generic pharmaceutical products." *Id.*

23. MSN Defendants have taken the costly, significant step of applying to the

FDA for approval to engage in future activities, including the marketing of the MSN ANDA Products, that will be purposefully directed at New Jersey and elsewhere in the United States.

24. On information and belief, MSN Defendants have systematic and continuous contacts with New Jersey; have established distribution channels for drug products in New Jersey; regularly and continuously conduct business in New Jersey, including by selling drug products in New Jersey, either directly or indirectly through their subsidiaries, agents, or affiliates; have purposefully availed themselves of the privilege of doing business in New Jersey; and derive substantial revenue from the sale of drug products in New Jersey.

25. On information and belief, if MSN's ANDA is approved, MSN Defendants will manufacture, market, promote, sell, offer for sale, import, use and/or distribute the MSN ANDA Products within the United States, including in New Jersey, consistent with MSN Defendants' practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, MSN Defendants regularly do business in New Jersey, and their practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. On information and belief, MSN Defendants' generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. On information and belief, the MSN ANDA Products will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the '733 patent in the event that the MSN ANDA Products are approved before the '733 patent expires.

26. On information and belief, MSNPI is registered with the State of New

Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400627791.

27. On information and belief, MSN Defendants derive substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and that are manufactured by MSN Defendants and/or for which MSN Labs and/or MSN Life and/or MSNPI is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which MSN Labs and/or MSN Life and/or MSNPI is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in New Jersey.

28. On information and belief, MSN Labs has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *See, e.g., Mitsubishi Tanabe Pharma Corporation et al. v. MSN Laboratories Private Limited et al.*, No. 3:19-cv-18958-FLW-DEA (D.N.J. Oct 14, 2019); *Chiesi USA, Inc. et al. v. MSN Pharmaceuticals Inc. et al.*, No. 2:19-cv-18564-MCA-MAH (D.N.J. Sept. 30, 2019); *BTG International Limited et al. v. MSN Pharmaceuticals Inc. et al.*, No. 2:18-cv-02372-KM-JBC (Feb. 20, 2018).

29. On information and belief, MSNPI has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *Mitsubishi Tanabe Pharma Corporation et al. v. MSN Laboratories Private Limited et al.*, No. 3:19-cv-18958-FLW-DEA (D.N.J. Oct 14, 2019); *Chiesi USA, Inc. et al. v. MSN Pharmaceuticals Inc. et al.*, No. 2:19-cv-18564-MCA-MAH (D.N.J. Sept. 30, 2019); *BTG International Limited et al. v. MSN Pharmaceuticals Inc. et al.*, No. 2:18-cv-02372-KM-JBC (Feb. 20, 2018).

30. This Court has personal jurisdiction over MSN Labs because the

requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Merck's claims arise under federal law; (b) MSN Labs is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) MSN Labs has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of MSN's ANDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over MSN Labs satisfies due process.

31. This Court has personal jurisdiction over MSN Life because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Merck's claims arise under federal law; (b) MSN Life is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) MSN Life has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of MSN's ANDA, participating in the preparation and submission of Drug Master File No. 33723 to the FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over MSN Life satisfies due process.

32. Venue is proper in this Court as to MSN Labs and MSN Life because MSN Labs and MSN Life are foreign entities who may be sued in any judicial district, including in the District of New Jersey. 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

33. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to MSNPI because, on information and belief, MSNPI has a regular and established place of business in New Jersey, and because, on information and belief, MSNPI has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the

asserted patents that will lead to foreseeable harm and injury to Merck by preparing or assisting in preparing MSN's ANDA in New Jersey and/or with the intention of seeking to market the MSN ANDA Products nationwide, including within New Jersey.

THE PATENT-IN-SUIT

34. Merck B.V. is the owner and assignee of the '733 patent, entitled "6-Mercapto-Cyclodextrin Derivatives: Reversal Agents For Drug-Induced Neuromuscular Block" (attached as Exhibit A). Merck B.V. has the right to enforce the '733 patent.

35. The '733 patent was duly and legally issued on January 28, 2014. The '733 patent was a reissue of U.S. Patent No. 6,670,340, which was duly and legally issued on December 30, 2003.

36. The '733 patent includes claims that recite 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, compositions containing 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, methods of using 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, and kits containing 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin.

37. 6-Per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin is also referred to as sugammadex.

38. The FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") currently lists the expiration of the '733 patent as January 27, 2021. On February 4, 2020, the United States Patent and Trademark Office ("PTO") issued a Notice Of Final Determination on the patent term extension ("PTE") application for the '733 patent, wherein the PTO determined that the '733 patent is eligible for 5 years of PTE (attached as Exhibit B). Therefore, after the PTE certificate is issued, the expiration of the '733 patent will be January 27, 2026.

THE BRIDION® DRUG PRODUCT

39. Organon is the holder of New Drug Application ("NDA") No. 022225, under which the FDA approved the commercial marketing of Bridion® (sugammadex) Injection ("Bridion®") on December 15, 2015, under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a). Bridion® is approved for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery. Bridion® is distributed in the United States by Merck Sharp and Dohme Corp., a wholly owned subsidiary of Merck & Co., Inc., in 200 mg/2 mL and 500 mg/5 mL strengths in a single-dose vial for bolus injection. A true and correct copy of the current prescribing information for Bridion® is attached as Exhibit C.

40. Bridion® is a first-in-class drug that works differently than prior agents used for the reversal of neuromuscular blockade. The active ingredient in Bridion®, sugammadex, is a modified cyclodextrin that acts by directly encapsulating, binding, and inactivating agents used by healthcare providers to induce neuromuscular blockade in patients undergoing surgery, e.g., rocuronium or vecuronium, to reverse their effects. After intravenous injection, Bridion® distributes through plasma and binds to such neuromuscular blocking agents ("NMBAs") to form a complex. This process reduces the amount of NMBA available to bind to nicotinic cholinergic receptors in the neuromuscular junction, resulting in the reversal of neuromuscular blockade.

41. By this mechanism, Bridion® also avoids several of the side effects associated with prior reversal agents, such as acetylcholinesterase inhibitors. Traditional reversal agents are co-administered with other agents to manage these side effects, but the co-administered agents can cause a number of additional side effects. Moreover, Bridion® is capable of reversing the complete and prolonged block of neuromuscular function (known as "profound block") that can occur with the administration of NMBAs. Further, intravenous administration of sugammadex

results in more rapid recovery from moderate or deep neuromuscular blockade in patients undergoing surgery who received rocuronium or vecuronium, as compared to neostigmine or succinylcholine. Because of at least these unique features, Bridion® has been viewed as a significant advance in the field of anesthesiology.

42. Bridion®, as well as methods of using Bridion®, are covered by one or more claims of the '733 patent. The '733 patent has been listed in connection with NDA No. 022225 in the FDA's Orange Book.

DEFENDANTS' ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

43. On information and belief, MSN Defendants have submitted or caused the submission of MSN's ANDA to the FDA under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the MSN ANDA Products, as a purported generic version of Bridion®, prior to the expiration of the '733 patent.

44. On information and belief, the FDA has not yet approved MSN's ANDA.

45. In the MSN Notice Letter, MSN Labs notified Merck of the submission of MSN's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Products prior to the expiration of the '733 patent.

46. In the MSN Notice Letter, MSN Labs acknowledged that the Reference Listed Drug for MSN's ANDA is Bridion®. Bridion® is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery.

47. In the MSN Notice Letter, MSN Labs also notified Merck that, as part of its ANDA, MSN Labs had filed a purported Paragraph IV Certification pursuant to 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV), with respect to the '733 patent.

48. On information and belief, MSN Labs submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '733 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Products.

49. In the MSN Notice Letter, MSN Labs stated that the MSN ANDA Products contain sugammadex as an active ingredient.

50. On information and belief, MSN Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, prepared and submitted MSN's ANDA, and intend to further prosecute MSN's ANDA. On information and belief, if the FDA approves MSN's ANDA, MSN Defendants will manufacture, distribute, promote, market, offer for sale, or sell the MSN ANDA Products within the United States, or will import the MSN ANDA Products into the United States. On information and belief, if the FDA approves MSN's ANDA, MSN Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the MSN ANDA Products in or into the United States.

51. Merck brings this action within forty-five days of receipt of the MSN Notice Letter. Accordingly, Merck is entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I – INFRINGEMENT OF THE '733 PATENT

52. Merck incorporates each of the preceding paragraphs 1–51 as if fully set forth herein.

53. The MSN ANDA Products, and the use of the MSN ANDA Products, are covered by one or more claims of the '733 patent, including at least claim 1 of the '733 patent,

because claim 1 of the ’733 patent encompasses the sugammadex utilized in the MSN ANDA Products.

54. In the MSN Notice Letter, MSN Labs did not contest infringement of claims 1-5, and 11-14 of the ’733 patent.

55. MSN Defendants’ submission of MSN’s ANDA with a Paragraph IV Certification for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Products in or into the United States before the expiration of the ’733 patent is an act of infringement of the ’733 patent under 35 U.S.C. § 271(e)(2)(A).

56. If approved by the FDA, MSN Defendants’ commercial manufacture, use, importation, sale, and/or offer for sale of the MSN ANDA Products in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the ’733 patent under 35 U.S.C. § 271(a)-(c).

57. On information and belief, MSN Defendants will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the MSN ANDA Products in or into the United States immediately and imminently upon approval of MSN’s ANDA.

58. The commercial manufacture, use, sale, offer for sale, or importation of the MSN ANDA Products in or into the United States would infringe one or more claims of the ’733 patent.

59. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the MSN ANDA Products in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the ’733 patent.

60. On information and belief, upon FDA approval of MSN's ANDA, MSN Defendants will, through their own actions or through the actions of their agents, affiliates, and subsidiaries, market and/or distribute the MSN ANDA Products to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, MSN Defendants will knowingly and intentionally accompany the MSN ANDA Products with a product label or product insert that will include instructions for using or administering the MSN ANDA Products, which are substantially similar to the instructions in the prescribing information for Bridion®, attached as Exhibit C, and which, if followed, will infringe the '733 patent. Accordingly, MSN Defendants will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the MSN ANDA Products to directly infringe the '733 patent. On information and belief, MSN Defendants will encourage acts of direct infringement with knowledge of the '733 patent and knowledge that MSN Defendants are encouraging infringement.

61. On information and belief, MSN Defendants plan and intend to, and will, actively induce infringement of the '733 patent when MSN's ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval. MSN Defendants' activities will be done with knowledge of the '733 patent and specific intent to infringe that patent.

62. On information and belief, MSN Defendants know that the MSN ANDA Products and proposed labeling are especially made or adapted for use in infringing the '733 patent, that the MSN ANDA Products are not a staple article or commodity of commerce, and that the MSN ANDA Products and accompanying proposed labeling are not suitable for substantial noninfringing use. On information and belief, MSN Defendants plan and intend to, and will, contribute to infringement of the '733 patent immediately and imminently upon approval of MSN's ANDA.

63. Notwithstanding MSN Defendants' knowledge of the claims of the '733 patent, MSN Defendants have continued to assert their intent to manufacture, use, offer for sale, sell, distribute, and/or import the MSN ANDA Products with its product labeling in or into the United States following FDA approval of MSN's ANDA prior to the expiration of the '733 patent.

64. The foregoing actions by MSN Defendants constitute and/or will constitute direct infringement of the '733 patent; active inducement of infringement by others of the '733 patent; and contribution to the infringement by others of the '733 patent.

65. On information and belief, MSN Labs, in concert with its agents, affiliates, and subsidiaries, including MSN Life and MSNPI, filed MSN's ANDA with a Paragraph IV Certification without adequate justification for asserting that the '733 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the MSN ANDA Products. On information and belief, MSN Defendants have acted with full knowledge of the '733 patent and without a reasonable basis for believing that they would not be liable for direct infringement of the '733 patent; active inducement of infringement by others of the '733 patent; and/or contribution to the infringement by others of the '733 patent. On information and belief, the direct and indirect infringement by MSN Defendants of the '733 patent was and is willful. MSN Defendants' conduct renders this case "exceptional" under 35 U.S.C. § 285.

66. Merck will be substantially and irreparably damaged by infringement of the '733 patent. Unless MSN Defendants are enjoined from directly infringing the '733 patent, actively inducing infringement of the '733 patent, and contributing to the infringement of the '733 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law, and considering the balance of hardships between Merck and MSN Defendants, a remedy in equity is warranted.

Further, the public interest would not be disserved by the entry of an injunction.

PRAYER FOR RELIEF

WHEREFORE, Merck requests the following relief:

(a) A judgment that the '733 patent has been infringed under 35 U.S.C. § 271(e)(2) by MSN Defendants' submission to the FDA of MSN's ANDA;

(b) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of the MSN ANDA Products, or any other drug product that infringes or the use of which infringes the '733 patent, be not earlier than the expiration date of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining MSN Defendants, and all persons acting in concert with MSN Defendants, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the MSN ANDA Products, or any other drug product covered by or whose use is covered by the '733 patent, prior to the expiration of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the MSN ANDA Products, or any other drug product that is covered by or whose use is covered by the '733 patent, prior to the expiration of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity, will infringe, induce the infringement of, and contribute to the infringement by others of the '733 patent;

(e) A declaration that MSN Defendants' commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the MSN ANDA Products, or

inducing or contributing to such conduct, would constitute infringement of one or more claims of the '733 Patent by MSN Defendants under one or more of 35 U.S.C. § 271(a), (b), and (c);

(f) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if MSN Defendants engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the MSN ANDA Products, or any product that infringes the '733 patent, or induces or contributes to such conduct, prior to the expiration of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A judgment that MSN Defendants willfully and deliberately infringed the '733 patent;

(h) A declaration that this is an exceptional case and an award of attorney's fees pursuant to 35 U.S.C. § 285;

(i) Costs and expenses in this action; and

(j) Such further and other relief as this Court may deem just and proper.

Dated: March 26, 2020
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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